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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,953	02/13/2001	R. Sanders Williams	UTSD:674US/SLH	2337

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	PAPER NUMBER
1653	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/782,953	Applicant(s) WILLIAMS ET AL.	
	Examiner Samuel W Liu	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-101* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 7-11 and 13-17, drawn to a method of screening for a modulator of binding of

myocyte enriched calcineurin interacting protein (MCIP) in a cell free system, are classified in class 435, subclass 7.1, and class 530, subclass 350.

II. Claims 1, 2-5 and 7-11 and 13-17, drawn to a method of screening for a modulator of binding of MCIP in a cell, are classified in class 435, subclass 7.1, class 424, subclass 93. 7, and class 530, subclass 350.

III. Claims 1, 6, 7-11 and 13-17, drawn to a method of screening for a modulator of binding of MCIP in an animal, are classified in class 435, subclass 7.1, class 530, subclass 350, and class 800, subclass 800/14.

IV. Claims 18-19, 24-26 and 29-34, drawn to a method of screening for a modulator of dephosphorylation of MCIP in a cell free system, are classified in class 530, subclass 335 and 402, and class 435, subclass 7.6.

V. Claims 18, 20-22, 24-34, drawn to a method of screening for a modulator of dephosphorylation of MCIP in a mammalian culture cell, are classified in class 530, subclass 335 and 402, and class 435, subclass 7.6 and 70.1, and class 424, subclass 9.322.

VI. Claims 18, 23, 24-26 and 29-34, drawn to a method of screening for a modulator of dephosphorylation of MCIP in non-human animal, i.e. a mammal, are classified in class 530, subclass 335 and 402, class 435, subclass 7.6, and class 800, subclass 14.

VII. Claims 35-40 and 43-45, drawn to a method of screening for a modulator of MCIP expression and modulating muscle cell growth in a cell via analyzing polynucleotide, are classified in class 514, subclass 2 and 11, class 424, subclass class 78.1, class 435, subclass 6, and class 604, subclass 19.

VIII. Claims 35 and 41-45, drawn to a method of screening for a modulator of MCIP expression and modulating muscle cell growth in a cell via analyzing polypeptide, are classified in class 514, subclass 2 and 11, class 424, subclass class 78.1, class 435, subclasses 7.1 and 7.8, and class 604, subclass 19.

IX. Claims 46-55, drawn to a method of screening for a modulator of MCIP expression and modulating muscle cell growth via transcriptional analysis, are classified in class 514, subclass 2 and 11, class 424, subclass class 278.1, and class 435, subclass 6.

X. Claims 46 and 56, drawn to a method of screening for a modulator of MCIP expression and modulating muscle cell growth in a non-human animal, i.e. a mammal, are classified in class 514, subclass 2 and 11, class 424, subclass class 278.1, and class 604, subclass 19.

XI. Claim 57, drawn to a method of modulating muscle cell growth via regulating MCIP binding to calcineurin, is classified in class 514, subclass 2 and 11, class 435, subclasses 7.1, 7.2 and 7.8, class 424, subclass 9.1class 278.1, and class 604, subclass 19.

XII. Claim 58, drawn to a method of modulating muscle cell growth in a mammal comprising a modulator for MCIP dephosphorylation administering the modulator to muscle cell, is classified in class 514, subclass 2 and 11, class 424, subclass class 278.1, and class 604, subclass 19.

XIII. Claims 59 and 61-69, drawn to a method of modulating muscle cell growth via modulating MCIP expression, are classified in class 514, subclass 2 and 11, class 424, subclass class 278.1, class 536, subclass 23.2, class 435, subclasses 69.1, 320.1 and 455, and class 436, subclass 94.

XIV. Claims 59-60 and 61-70 and 61-69, drawn to a method of modulating muscle cell growth via modulating MCIP expression in an animal, are classified in class 514, subclass 2 and subclass class 278.1, class 536, subclass 23.2, class 435, subclasses 69.1, 320.1 and 455, class 436, subclass 94, and class 800, subclass 14.

XV. Claims 71-75, drawn to isolated MCIP1 polynucleotide promoter, are classified in class 536, subclass 23.1, class 514, subclass 44, class 435, subclasses 69.1.

XVI. Claim 76, drawn to a method of screening for modulator of MCIP1 expression, is classified in class 514, subclass 2 and 11, class 424, subclass class 278.1, class 536, subclass 23.2, class 435, subclasses 69.1, 320.1 and 455, and class 436, subclass 94.

XVII. Claims 77-83, drawn to a method of treating a disease state comprising administering an agent, are classified in class 514, subclass 2, class 435, subclass 21, class 424, subclass 9.1, and class 604, subclass 19.

XVIII. Claims 77 and 84-86, drawn to a method of treating a disease state comprising administering an agent that is a polynucleotide sequence, are classified in class 514, subclass 1 and 2, class 530, subclass 23.1 and 23.4, class 424, subclass 9.1, and class 604, subclass 19.

XIX. Claims 87-98, drawn to an isolated DNA, a MCPI promoter, an expression cassette sequence and a host expressing the cassette sequence, are classified in class 536, subclass 23.1, class 435, subclass 69.1, 320.1, 252.3 and 325^{+}.

XX. Claims 99 and 100, drawn to an isolated MCIP polypeptide, are classified in class 530, subclass 350, class 514, subclass 2.

XXI. Claim 101, drawn to a method of treating cardiac hypertrophy comprising administering to a subject an agent that inhibit MCIP binding to calcineurin, are classified in class 514, subclass 1 and 2, class 530, subclass 23.1 and 23.4, class 424, subclass 9.1, and class 604, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions XIX and XX are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention XIX is drawn to polynucleotide while Invention XX is drawn to polypeptide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions XV and XX are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention XIV is drawn to polynucleotide promoter sequence whereas Invention XX is drawn to polypeptide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to

exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions XV and XIX are different in both sequence structure and transcriptional function; promoter is a segment functions a regulatory module for transcriptional regulation whereas the DNA coding sequence acts as a template for synthesis of mRNA and polypeptide. The biopolymers of each invention would be expected to exhibit different physical and biological cal properties, and are capable of separate manufacture or use.

Inventions I, II, III, V, VI, VII, VIII, IX, X, XI, XII , XIII, XIV, XVI, XVII, XVIII and XXI are related as different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Inventions I- XIII since they constitute patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

Inventions XIX and XV are related to Inventions VII, VIII, IX, X, XIII, XIV, XVI and XVIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated polynucleotide can be immobilized on the DNA microarray chip for genomic typing analysis, for example.

Inventions XIX and XV are unrelated to Inventions I-VI, XI, XII and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, cellular mechanism of polynucleotide transcriptional regulation is different from mechanism of protein-protein interaction and enzymatic mechanism.

Invention XX are related to Inventions I, II, II, IV, V, VI, XI, XII and XIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated polypeptide can be immobilized on a gold surface for surface plasma resonance study for real time protein-protein interaction, for example.

Inventions XX is unrelated to Inventions VII, VIII, IX, X, XIII, XIV, XVI and XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, mechanism of protein-protein interaction and enzymatic mechanism, e.g. phosphatase, are different/distinct from mechanism of polynucleotide directed mRNA synthesis and polypeptide synthesis as well as polynucleotide involved transcriptional regulation.

Additional Election Under 35 USC 121

Regardless of the elected group, applicant is required under 35 US 121 (1) to make the following elections with respect to patentably distinct inventions; and (2) to list all claims readable thereon including those subsequently added.

If Group V is elected, applicant is required under 35 US 121 (1) to elect one protein from Claim 27, because each protein participates in different cellular singling pathway, e.g. calmodulin-dependent protein kinases (CaMK) and glycogen synthase kinase 3 (GSK3) involve in different signaling pathways and distinct disease states, e.g. CaMK plays a role in wobbler spinal muscular atrophy whereas GSK3 plays a key role in promoting neurodegeneration and in Alzheimer's disease.

If group XIII or XIV is elected, applicant is required under 35 US 121 (1) to elect a promoter from Claim 65 because these promoter functions differently based on host cell type, vector biological environment (e.g. enhancer, operator and transcriptional factor(s) etc) and promoter strength *per se*.

If group XIX is elected, applicant is required under 35 US 121 (1) to elect a promoter from Claims 90 and 98 because these promoter functions differently based on host cell type, vector biological environment (e.g. enhancer, operator and transcriptional factor(s) etc) and promoter strength *per se*.

If group XVII is elected, applicant is required under 35 US 121 (1) to elect an antagonist molecule for calcineurin from Claim 78 since each molecule is pharmacologically different in their structure, efficacy and pharmacokinetics and pharmacodynamics absent factual indicia to the contrary.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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September 30, 2002